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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,145	04/12/2002	Beth E Borowsky	59338-B-PCT-US/JPW/FHB	8082

45821 7590 04/05/2005

SYNAPTIC PHARMACEUTICAL CORPORATION
ATTENTION: STEPHEN G. KALINCHAK, LEGAL
215 COLLEGE ROAD
PARAMUS, NJ 07652

EXAMINER	
HAMUD, FOZIA M	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,145	BOROWSKY ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/21/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-9,19,21-25,28-32 and 35-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9,19,21-25,28-32 and 35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2001* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/25/02; 04/08/01*; 11/28/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Status of Claims:

1a. Claims 6, 10-18, 20, 26-27, 33-34 and 38-170 have been cancelled. Claims 1-5, 7-9, 19, 21-25, 28-32, and 35-37 are pending and under consideration.

Election/Restriction:

2a. Applicant's election with traverse of the invention of Group I (all of the pending claims are) drawn to this invention), drawn to an isolated nucleic acid encoding the polypeptide comprising the amino acid sequence set forth in SEQ ID NO:6, an expression vector comprising said nucleic acid and comprising said vector, a host cell, filed on 10 October 2004 is acknowledged.

Applicants' traversal is on the grounds that the sequences of the human, rat and mouse SNORF33 receptors share significant homology and that they also share biological function because they all bind to the same ligands. Applicants also argue that there is no serious burden on the Examiner to search and examine all of the Groups because a search of prior art with regard to group I would reveal whether any prior art exists for Group II or III.

This argument is not found persuasive. Inventions of Groups I-III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function which cannot be exchanged. Contrary to Applicants' argument, a search for one of the Groups would not necessarily reveal art to the other Group. Furthermore, the rat, human and mouse sequences do not appear to share significant homology. A search conducted for the polypeptide of

SEQ ID NO:6, revealed that SEQ ID NO:6 shares 77.7% and 74.8% homology to SEQ ID NO:4 and SEQ ID NO:37, respectively. Therefore, it would not be expected that polypeptides that share 77.7% or 74.8% homology would display similar biological function, or would bind to their ligand with the same affinity. The restriction requirement is still deemed proper and is therefore made FINAL.

All of the pending claims are drawn to the elected invention, therefore, all of the pending claims will be searched and examined.

Sequence Compliance:

3a. This case now complies with the requirements of the sequence rules under 37 CFR §1.821-§1.825.

Information Disclosure Statement:

4a. All of the references cited on the information disclosure statements filed on November 28 2001, 25 November 2002 and 08 April 2004 have been considered.

5. ***Priority:***

5a. The instant Application is a national stage of PCT/US00/14654 filed 35 U.S.C. § 371, on 26 May 2000. Based on the information given by Applicants and an inspection of the parent applications, the Examiner has concluded that the subject matter defined in this application is not supported by the disclosure of any of the priority applications, because, although the prior applications disclose the polypeptide of SEQ ID NO:5 and the encoded polypeptide of SEQ ID NO:6, none of the parent applications provide a specific and substantial asserted utility or a well established utility for the claimed invention. Accordingly, the subject matter defined in claims -5, 7-9, 19, 21-25, 28-32,

and 35-37, is afforded an effective filing date of 26 May 2000, which is the filing date of PCT/US00/14654.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 05/14/00, which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 05/14/00.

Claim Rejections - 35 U.S.C. § 101:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6a. Claims 28-29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 28-29 recite " a cell comprising...", which encompasses the cell, as it occurs in nature, for example, as a gene therapy patient. However, since Applicants do not intend to claim a naturally occurring products amendment of the claims to show the hand of man would obviate this rejection. It is suggested that claim 28 to recite " an isolated cell..... .....". Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112, first paragraph:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7a. Claims 1-5, 7-8, 19, 21-25, 28-32, 35-37 are ejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1 recites a "...a plasmid pcDNA3.1-hSNORF33-f (ATCC Patent Depository No. PTA-398"; or a "...a plasmid pEXJ-hSNORF33-f (ATCC Patent Depository No. PTA-570". . It is apparent that these plasmids are required to practice the claimed invention, because they are required to produce the encoded protein. As such said plasmids must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If these plasmids are not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of these plasmids.

The specification, provides an ATCC Patent Depository Nos for the claimed plasmids, however, the specification lacks complete deposit information for the deposit of said plasmids. If a deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide

assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that (a) during pendency of the application, access to the invention will be afforded to the Commissioner upon request, (b) all restrictions upon availability to the public will be irrevocable removed upon granting of the patent, © the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer, (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807) and (e) the deposit will be replaced if it should ever become inviable.

Furthermore, although the specification provides two different plasmids and assigns two different ATCC Patent Depository numbers, it discloses that both of these plasmids encode human SNORF-33 receptor. However, there is no description as to the difference between these plasmids. Do they both encode the polypeptide of SEQ ID NO:6?

7b. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention.

The instant specification discloses the construction of plasmids encoding the polypeptide of SEQ ID NO:6, which have specific structures. The instant specification discloses that the human SNORF33 receptor gene comprises the nucleic acid

sequence shown in Figures 5A-5B or contained in plasmid pcDNA3.I-hSNORF33-f (ATCC Patent Depository No. PTA- 398), or contained in plasmid pEXJ-hSNORF33-f (ATCC Patent Depository No. PTA-570), (pages 41-42). The written description in the instant case only satisfies an isolated nucleic acid encoding the polypeptide of SEQ ID NO:6, said nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:5. However, the written description does not satisfy claim 4, which is drawn to a "genomic DNA". Accordingly, one of ordinary skill in the art would not be able to visualize the structures of the encompassed genomic DNA as recited in claim 4.

Thus, conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention.

To satisfy the written description requirement, an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of invention. Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997); Hyatt v. Boone, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998). Furthermore, In The Reagents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. Adequate written description requires more than a mere statement that it is part of the invention. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the

recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Thus, instant claim 4 fails to meet the written description provision of 35 U.S.C. 112, first paragraph.

Conclusion:

8. No claim is allowed. The claims are free of prior art.

Claim 9 depends from a rejected claim 1. Claim 9 would be allowable if rewritten in an independent form.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
31 March 2005

JANET ANDRES
PRIMARY EXAMINER